

### INTERVIEW SUMMARY

On April 20, 2004, the undersigned attorney for Applicant participated in a telephonic interview with Examiner Marc Patterson, to discuss the Action mailed January 29, 2004, in which the Examiner issued a 35 U.S.C. §103 rejection over the Reed reference. Prior to the January 29, 2004 Action, the Examiner had rejected independent claim 19 as anticipated by Reed under 35 U.S.C. §102. During the interview, the Examiner was asked to identify the limitation of claim 19 not disclosed in Reed. It was agreed that the Examiner would issue a Supplemental Office Action to clarify the rejection over Reed, prior to Applicant's response.

### REMARKS

Withdrawn method claims 24-34 are hereby canceled for consideration in a divisional application, leaving claims 2-23 pending for examination.

#### Rejection under §102(b)

Claims 2-12 and 16-23 are rejected under 35 U.S.C. §102(b) as being anticipated by Reed et al. (U.S. Patent 5,312,456; "Reed"). All claims are also rejected under 35 U.S.C. §103(a) as obvious over Reed, either alone or in view of various other references. Specifically, claims 2, 3, 5-9, 11, 12 and 18 are rejected as obvious over Reed alone, claim 13 is rejected over Reed in view of Fye (U.S. Patent 5,031,609), and claims 14 and 15 are rejected as obvious over Reed in view of Coates (U.S. Patent 4,219,019).

Reed discloses "micromechanical barbs" 16 each having a head 20 disposed upon a support 18 extending from a base 22. The head has extremity portions 26 for interlocking with other barbs or forming a locking connection with another object.<sup>1</sup> The head may have a pointed central portion 24, for piercing skin, for example.<sup>2</sup>

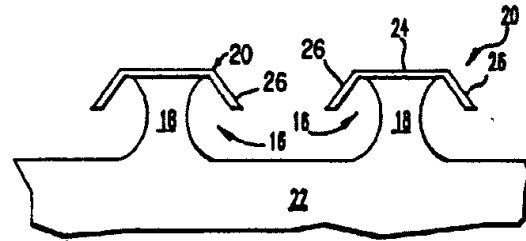


FIG. 2

As for suitable materials, Reed states that

the base 22, head 20 and support 18 are made of a rigid material. The rigid material can be, for instance, metal, ceramic, plastic, composite material or alloy. The metal could be steel, the ceramic could be aluminum oxide, the composite material could be graphic fiber matrix composite and the plastic polysulfone. Preferably, the base and support are made out of Si and the head is made out of SiO<sub>2</sub>.<sup>3</sup>

It is on this particular passage in Reed that the Examiner relies in his assertion that Reed discloses penetrating elements (Reed's barbs 16) formed, with their retention barbs (Reed's head extremity portions 26), of a single plastic resin.

Reed's sole disclosed method of making the "micromechanical barbs" is by a photochemical etching process in which layers of different materials are sequentially etched to leave "barbs" of the desired shape.<sup>4</sup> First, a substrate 34 (such as Si or steel) is provided with "a layer 36 of a *second* material, such as SiO<sub>2</sub>, thereon."<sup>5</sup> A sequence of steps is performed to configure the layer of the second material as shown in Fig. 9c.

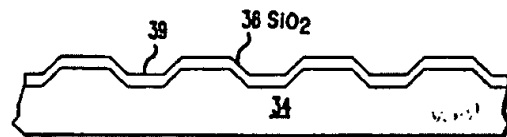


FIG. 9c

<sup>1</sup> See Reed et al. at col. 3, lines 35-39.

<sup>2</sup> Id., col. 4, lines 28-32.

<sup>3</sup> Id., col. 3, lines 39-46.

<sup>4</sup> See Reed et al. at col. 5, lines 39-59 and col. 6, lines 40-60.

<sup>5</sup> Id., col. 5, lines 40-42, emphasis added.

“Next, there is the step of removing portions of the layer 36 at essentially the center of the lowest points of the frustum of the layer 38 [sic, 36],”<sup>6</sup> ostensibly to expose the substrate 34 for etching. “Then, there is the step of removing portions of the substrate 34 *but not the layer 36* such that a plurality of barbs 16 is created as

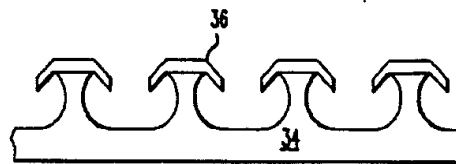


FIG. 9d

shown in Fig. 9d.”<sup>7</sup> The detailed example of the micromachining method disclosed in column 6 of the Reed patent clearly identifies the final step of removing portions of the substrate without removing the heads as an isotropic etch that results in “considerable lateral undercutting”.<sup>8</sup>

Contrary to the Examiner's assertion, Applicant submits that the limitation “formed integrally from a single plastic resin” does not read on Reed's skin attachment members. In making the rejection, the Examiner states that Reed's barbs “comprise a single plastic resin (polysulfone)” but Applicant respectfully points out that “comprising a single plastic resin” is an open limitation that would read on elements each formed of many different resins, and is not the feature recited in the rejected claims. Rather, the associated limitation is that the array of skin penetrating elements, including each retention barb, is *formed integrally from a single plastic resin*. In other words the elements, including their barbs, are each structurally of a single resin, as opposed to the shanks of the elements being of one resin, and the barbs of another, as in Reed. In Reed's primary illustration, both the heads and supports can be said to *comprise* silicone, for example, but it can not be said that they are not *formed of* a single layer of silicone.

As evidenced by the declaration previously submitted under 37 C.F.R. §1.132 (hereinafter the “Harvey Declaration”), the masking and etching technique taught by Reed could only be used to form overhanging barbs if the underlying substrate (e.g., substrate 34) is more susceptible to the applied etchant than an overlying layer (e.g., layer 36). In other words, the method taught by Reed necessitates forming the heads of a different material than the substrate,

<sup>6</sup> Id., col. 5, lines 54-57.

<sup>7</sup> Id., col. 5, lines 57-59, emphasis added.

<sup>8</sup> Id., col. 6, lines 50-51.

in order to obtain the lateral undercutting disclosed by Reed.<sup>9</sup> Therefore, Reed does not disclose or fairly suggest at least the limitation of "wherein the array of skin penetrating elements, including each retention barb, is formed integrally from a single plastic resin."

Not only does Reed not disclose such a feature, the cited reference does not enable the invention as claimed.<sup>10</sup> Specifically, Reed does not enable making or using a skin attachment member with penetrating elements formed integrally, together with their retention barbs, of a single plastic resin, as the only barb creation methods taught by Reed are not able to create skin penetrating elements of the structure claimed. Applicant has submitted the Harvey Declaration as evidence to support this statement, in which Mr. Harvey states that

Based on my review of the entire disclosure of the '456 patent and my experience in techniques for shaping/forming plastics, I conclude that the '456 patent in no way teaches or suggests a technique for manufacturing a barb in which the base 22, head 20, including central 24 and extremity portions 26, and support 18 are all formed integrally of a single plastic resin.<sup>11</sup>

The Examiner has failed to give any rebuttal to this evidence. Accordingly, Applicant respectfully submits that the Reed reference does not meet the requirements of an anticipatory reference under 35 U.S.C. §102(b) with respect to any of the pending claims, and that the rejection under 35 U.S.C. §102(b) is improper and should be withdrawn.

### Rejections under §103

A conclusion of obviousness requires that the cited reference or combination of references relied upon be so enabling as to place the public in possession of the claimed invention.<sup>12</sup> Regarding the claims rejected over Reed as a single reference, Applicant has

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<sup>9</sup> See the Harvey Declaration at paragraph 6.

<sup>10</sup> See Akzo N.V. v. U.S. Int'l Trade Comm'n, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1987) ("[T]he prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.")

<sup>11</sup> Harvey Declaration, paragraph 7.

<sup>12</sup> See Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 13 USPQ2d 1301 (Fed. Cir. 1989) ("In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method."), In re Epstein, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (The references "must be enabling, thus placing the alleged disclosed matter in the possession of the public."), and In re Hoeksema, 399 F.2d 269, 274 (CCPA 1968)

already shown that Reed does not enable the claimed invention, and therefore the single-reference §103 rejections over Reed should also be withdrawn.

Furthermore, none of the suggested combinations of references with Reed to reject claims under 35 U.S.C. §103 enable the claimed invention, as none of the secondary references provide any insight into how one of ordinary skill in the art could have produced a skin attachment member of the structure claimed. Therefore Applicant respectfully submits that the Examiner has not produced a *prima facie* case of obviousness of the claims rejected over combinations of references, and asks that these rejections also be withdrawn.

With regard to claims 2, 3 and 22, Applicant disagrees with the Examiner's broad assertion, citing In re Dailey, that a recited limitation directed to a change in shape is generally obvious to one of ordinary skill in the art.<sup>13</sup> The real issue is whether the claimed limitation is novel and non-obvious over the prior art. The Applicants in In re Dailey lost their case by not being able to show that the 'less than hemispherical' shape of their design was in any way "significant."<sup>14</sup> Applicant here, on the other hand, has explained the significance of the recited shape with respect to skin penetration and retention, as well as limiting the detrimental effect to the skin due to the penetration.<sup>15</sup>

Similarly, with regard to claims 5-9, 11, 12 and 18, the Examiner states that Reed fails to disclose the respective limitations, but that one of ordinary skill in the art would recognize the advantage of varying the diameter, length and angle of point of the penetrating element, the thickness of the backing and number of elements per area to obtain a desired range of flexibility.<sup>16</sup> While Applicant submits that these claims are allowable at least as depending from

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<sup>13</sup> In re Dailey was a simple affirmation by the CCPA in 1966 of a board decision that the particular configuration of a disposable nursing container was "not significantly novel" over the prior art, and notably contained no broad statement concerning the obviousness of changes in shape. The only relevant statement by the court was that the Dailey had "presented no argument which convinces us that the particular configuration of their container is significant or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious..." (In re Dailey, 357 F.2d 669 at 672). It is regrettable that such a case is characterized by the MPEP as standing for such a proposition, and that few Examiners read the case.

<sup>14</sup> See In re Dailey, 357 F.2d 669 (CCPA 1966).

<sup>15</sup> See Applicant's Specification, page 4, line 15, for example.

<sup>16</sup> The Examiner refers to Reed, col. 4, lines 47-48 as teaching that maximum flexibility is desired, but this passage simply refers to the desirability of grooving an annulus secured inside a blood vessel, such that "when the blood vessel 63 is attached under pressure to the annulus 52, the annulus breaks apart along the grooves", as noted in lines

an allowable base claim 19, for the record Applicant traverses the legitimacy of this rejection as being unsubstantiated by the prior art of record. There is simply no evidence presented for the conclusion that all of these parameters are merely matters of 'routine optimization' or design choice, or are even all related to flexibility, as advanced by the Examiner.

Regarding claims 13, 14 and 15, Fye and Coates disclose bandages of various materials (e.g., nylon and polyethylene terephthalate, respectively). However, neither reference overcomes the above-described deficiencies of Reed as concerning claim 19, discussed above, and Applicant submits that these dependent claims are therefore also allowable over the cited references.

Please apply any other charges or credits to deposit account 06-1050, referencing matter 05918-153001.

Respectfully submitted,

Date:

May 24, 2004



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